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K102844

510 (k) SUMMARY

OCT 2 9 2010

Applicant:

Bisco, Inc.
1100 W. Irving Park Road
Schaumburg IL, 60193

Contact Person:

Michelle Schiltz-Taing
Tel: 847-534-6000
Fax: 847-534-6111

Date Prepared: 27 September 2010

Device Name:

Trade Name:	All-Bond 3
Common Name:	Dual-Cure Universal Adhesive System
Product Code:	KLE
Classification Name:	Resin tooth bonding Agent
Regulation Number:	Class II per 21 CFR 872.3200
Classification:	II
Classification Panel:	Dental

Predicate Device:

All-Bond 3 is substantially equivalent to All-Bond 2/All Bond XL from Bisco, Inc. Schaumburg IL (K910860).

Indications for Use:

- All Direct Restorations
- All Indirect Restorations
- Intra-oral Repair
- Desensitizing/sealing of tooth structure

Description of Applicant Device:

All-Bond 3 is an ethanol based dual-cured adhesive system that is compatible with all dental materials.

Technological Characteristics

All chemical components of All-Bond 3 are based upon industry standard monomer chemistry and are found in legally marketed predicate device All-Bond 2/All Bond XL (K910860). A comparison of the chemical composition of All-Bond 3 to the predicate device is provided in Table 1.

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Table 1

Chemical Composition	All Bond 2	All Bond XL	All-Bond 3
Light Cure	X	X	X
Self Cure	X	X	X
Methacrylate resin based	X	X	X
Contains Ethanol Solvent	X	X	X
Contains Acetone Solvent	X		

Performance Data:

They physical/mechanical properties of All-Bond 3 were tested in the lab using either QA/QC or R&D test protocols. The information provided in this 510(k) of All-Bond 3 compared to All Bond 2/All Bond Xli demonstrated that All-Bond 3 performs as well as or better than the predicates. A comparison of the physical/mechanical properties is included in Table 2.

Table 2:

Physical / Mechanical Property Comparison	All Bond 2	All Bond XL	All-Bond 3
Component 1 is a thin solution	X	X	X
Component 2 is a thin solution	X		
Component 2 is a thick solution		X	X
Low Viscosity when mixed 1:1	X	X	X
Dental Substrate Priming/Wetting Agent	X	X	X
Bonding agent to tooth structure	X	X	X

Biocompatibility:

Biocompatibility testing was conducted to determine the safety of All-Bond 3 using FDA guidelines and ISO 4049:2009. The conclusion of the safety evaluation and subsequent biocompatibility testing is that All-Bond 3 is safe for its intended use.

Conclusion:

The information provided in this 510(k) submission demonstrates that All-Bond 3 is substantially equivalent to the predicate device All Bond 2/All Bond XLi (K910860) in terms of intended use, indications for use, chemical composition and physical properties.

It is concluded that the information supplied in this submission has proven the safety and efficacy of this product.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Michelle Schiltz-Taing
Regulatory Affairs Coordinator
Bisco, Incorporated
1100 West Irving Park Road
Schaumburg, Illinois 60193

OCT 29 2010

Re: K102844
Trade/Device Name: All-Bond 3
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: September 27, 2010
Received: September 29, 2010

Dear Ms. Schiltz-Taing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K102844

OCT 29 2010

Device Name: All Bond 3

Indications for Use:

The principle uses of **All Bond 3** are:

- All Direct Restorations
- All Indirect Restorations
- Intra-oral Repair
- Desensitizing/sealing of tooth structure

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

)ivision Sign-Off)
vision of Anesthesiology, General Hospital
ection Control, Dental Devices

0(k) Number: K102844